

2006. Misbranding of Paulette's Special Tablet Compound. U. S. v. 11 $\frac{1}{2}$ Dozen Packages of Paulette's Special Tablet Compound. Default decree of condemnation and destruction. (F. D. C. No. 20229. Sample No. 53209-H.)

LABEL FILED: June 6, 1946, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about April 12, 1946, by the Youngs Rubber Corporation, Inc., from New York, N. Y.

PRODUCT: 11 $\frac{1}{2}$ dozen packages of *Paulette's Special Tablet Compound* at Nashville, Tenn. Examination showed that the tablets consisted essentially of a laxative plant drug such as aloes, iron sulfate, and myrrh, coated with calcium and magnesium carbonates.

LABEL, IN PART: (Package) "Contents 24 Tablets Paulette's Brand Special Tablet Compound."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the reason for the use of the article; and, Section 502 (f) (2), it failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, since the article was essentially a laxative and since the warning "Not for use in pregnancy or appendicitis" was not an adequate warning to inform users that the article should not be taken in case of nausea, vomiting, abdominal pain or other symptoms of appendicitis. The labeling further failed to warn that frequent or continued use of the article may result in dependence upon laxatives.

DISPOSITION: October 22, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2007. Misbranding of B-I-F Combination. U. S. v. 42 Cartons of B-I-F Combination. Default decree of condemnation and destruction. (F. D. C. No. 19946. Sample No. 993-H.)

LABEL FILED: May 27, 1946, Southern District of Florida.

ALLEGED SHIPMENT: On or about July 25, 1945, and January 3, 1946, by W. C. Hughes and Co., Inc., from Baltimore, Md.

PRODUCT: 42 cartons, each containing 2 bottles, of *B-I-F Combination* at Miami, Fla. Examination showed that one of the bottles in the carton contained "B-I-F Emulsion," which consisted essentially of balsam of copaiba, oil of cassia, sugar, glycerin, water, a gum, and a potassium compound; and that the other bottle contained "B-I-F Injection," which consisted essentially of zinc acetate, glycerin, and a small proportion of carbolic acid and water, colored with caramel. A leaflet entitled "B. I. F. Combination" was enclosed in some of the cartons.

LABEL, IN PART: (Bottles) "Purchasers wishing to avoid attention in the use of this article, are advised to place the bottle in water a few moments after which this label can readily be removed." (Leaflet contained in some cartons) "B-I-F Combination An Emulsion (For Internal Use) An Injection (with Syringe) Directions Shake the bottle containing the Injection which is red, fill the syringe full, and inject the contents slowly into the urinal passage, holding the syringe in the right hand. Allow the medicine to remain 20 or 30 seconds. The Emulsion which is white, should be taken internally three times a day, before meals, in teaspoonful doses, in the morning on arising, at noon and at bedtime. The injection should be used about the same time, and always after passing water."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling created the false and misleading impression that the product would be efficacious in the treatment of gonorrhea, whereas it would not be efficacious for such purpose; and, Section 502 (f) (1), the labeling of the portion that was not accompanied by the leaflet failed to bear adequate directions for use.

DISPOSITION: August 19, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2008. Misbranding of Dupree Brand Pills. U. S. v. 67 Boxes, 114 Boxes, and 34 Packages of Dupree Brand Pills. Default decrees of condemnation and destruction. (F. D. C. Nos. 19944, 19945. Sample Nos. 19755-H, 43923-H, 43924-H.)

LIBELS FILED: May 28, 1946, Southern District of California and District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of January 11 and May 9, 1946, by the Dupree Medical Co., from New York, N. Y.

PRODUCT: 34 packages of *Dupree Double Strength Pills* at St. Paul, Minn., and 67 Boxes of *New Formula Pills* and 114 boxes of *Extra Strength New Formula Pills* at Los Angeles, Calif. Examination showed that the products consisted essentially of yohimbin hydrochloride, asafetida, and a laxative plant drug. In addition, the *New Formula Pills* contained metallic iron, and the *Double Strength* and *Extra Strength Pills*, which were apparently the same product under slightly different labels, contained iron sulfate.

LABEL, IN PART: (New Formula Pills) "Yohimbin hydrochloride, 1/24 grain, dried iron sulfate, asafetida and aloe"; (Double Strength Pills) "Yohimbin Hydroch. 1/16 gr., Asafetida, Dried Iron Sulfate, Aloes Soc."; and (Extra Strength Pills) "Yohimbin Hydroch. Gr. 1/16 Dried Iron Sulfate, Asafetida, Aloes Soc."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the products failed to bear adequate directions for use since it failed to state why the articles were to be used; *New Formula Pills*, misbranding, Section 502 (a), the label statement, "Each pill contains * * * dried iron sulfate," was false and misleading since the product did not contain iron sulfate; and, Section 502 (e) (2), the product was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the label failed to reveal the presence of metallic iron.

DISPOSITION: July 29 and September 25, 1946. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

2009. Misbranding of West's Imported Sea Vegetable Tablets and various other drugs. U. S. v. Various Quantities of West's Imported Sea Vegetable Tablets, etc. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 19509. Sample Nos. 59818-H to 59833-H, incl., 59836-H, 59837-H, 59861-H to 59863-H, incl.)

LIBEL FILED: April 17, 1946, Western District of Pennsylvania; libel amended July 23, 1946.

ALLEGED SHIPMENT: Between the approximate dates of January 16 and February 26, 1946, by Mineralized Foods, Inc., from Baltimore, Md., and by Sherman Foods, Inc., from New York, N. Y.

PRODUCT: 1 bulk package and 69 bottles of *West's Imported Sea Vegetable Tablets*, 1 bulk package and 69 bottles of *West's Sodeom Vitaminized*, 1 bulk package and 30 bottles of *West-Aid*, 1 bulk package and 30 bottles of *West's Sea-Vo-Kra Tablets*, 1 bulk package and 30 bottles of *West's D-X Tablets*, 54 bottles of *West's Ferrolene*, 51 bottles of *West's Kalseom*, 43 bottles of *West's FYA Tablets*, 12 bottles of *West-Lax*, 5 1-pound cartons of *West's Vi-Linn (Chocolate)*, 5 1-pound cartons of *West's Vi-Linn (Banana)*, 74 bottles of *West's Sodeom*, 51 bottles of *West's Sea Vegecene*, 2 bottles of *West's Mar-Glo Tablets*, and 4 1-pound cartons of *West-Co.*, at Pittsburgh, Pa. Each of the bulk packages contained 5,000 tablets, the bottles of the *Sea Vegecene* were in 2-, 5-, and 8-ounce sizes, and the bottles containing the other products were in 100-, 125-, 240-, 300-, 400-, and 500-tablet sizes. The *Sea Vegecene*, *Ferrolene*, *Kalseom*, *FYA Tablets*, and *Sodeom* had been shipped in bulk containers and repacked by the dealer into bottles before seizure.

The sale of these products at Pittsburgh was promoted through lectures given by Mr. N. S. West, who was the active individual in Mineralized Foods, Inc., and at those lectures Mr. West recommended the products for use in the treatment of certain specific conditions.

LABEL, IN PART: "West's Imported Sea Vegetable Tablets (Edible Sea Plants)," "West's Sodeom is a trade name for a blend of West's Imported Sea Vegetation (Edible Sea Plants) carefully blended with added Vitamin A (Ester) and Vitamin C (Ascorbic Acid)," "West-Aid is a trade name for a blend of West's Imported Sea Vegetation (Edible Sea Plants) carefully blended with added Brewer's Yeast, Wheat Embryo and Vitamin B-1 (Thiamin)," "West's Sea-Vo-Kra Tablets Consists of a blend of West's Imported Sea Vegetation (Edible Sea Plants) in combination with Okra," "West's 'D-X' Tablets * * * Consists of an imported variety of West's Sea Vegetation (Edible Sea Plants)